



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Evan Gustow et al.  
Title: NANOPARTICULATE TOPIRAMATE  
FORMULATIONS  
Appl. No.: 10/766,960  
Filing Date: 01/30/2004  
Examiner: Unassigned  
Art Unit: 1615

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document, except as noted below, is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.*

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

**RELEVANCE OF EACH DOCUMENT**

All of the documents are in English.



Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date Aug. 16, 2004

FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 672-5538  
Facsimile: (202) 672-5399

By   
 Michele M. Simkin *Reg No 35,264*  
Attorney for Applicants  
Registration No. 34,717

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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

Use as many sheets as necessary)

Sheet 1 of 3

## Complete if Known

Application Number	10/766,960
Filing Date	01/30/2004
First Named Inventor	Evan Gustow
Group Art Unit	1615
Examiner Name	Unassigned
Attorney Docket Number	029318-0999

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A1	4,783,484		VIOLANTE ET AL.	11/08/1988	
	A2	4,826,689		VIOLANTO ET AL.	05/02/1989	
	A3	4,997,454		VIOLANTE ET AL.	03/05/1991	
	A4	5,145,684		LIVERSIDGE ET AL.	09/08/1992	
	A5	5,298,262		NA ET AL.	03/29/1994	
	A6	5,302,401		LIVERSIDGE ET AL.	04/12/1994	
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	A13	5,349,957		YUDELSON	09/27/1994	
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	A26	5,518,187		BRUNO ET AL.	05/21/1996	
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	A29	5,525,328		BACON ET AL.	06/11/1996	
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	A31	5,543,133		SWANSON ET AL.	08/06/1996	
	A32	5,552,160		LIVERSIDGE ET AL.	09/03/1996	
	A33	5,560,931		EICKHOFF ET AL.	10/01/1996	
	A34	5,560,932		BAGCHI ET AL.	10/01/1996	
	A35	5,565,188		WONG ET AL.	10/15/1996	
	A36	5,569,448		WONG ET AL.	10/29/1996	
	A37	5,571,536		EICKHOFF ET AL.	11/05/1996	
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	A39	5,573,750		SINGH	11/12/1996	
	A40	5,573,783		DESIENO ET AL.	11/12/1996	
	A41	5,580,579		RUDDY ET AL.	12/03/1996	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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				Filing Date	01/30/2004
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				Examiner Name	Unassigned
Sheet	2	of	3	Attorney Docket Number	029318-0999

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Examiner Signature		Date Considered	
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<b>Sheet</b>	3	<b>of</b>	3		

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	A75	WO	00/72973	A1	NANOSYSTEMS/DIVISION OF ELAN PHARMACEUTICAL TECHNOLOGIES	12/07/2000		
	A76	WO	02/098565	A1	ELAN PHARMA INC.	12/12/2002		

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A77	BRAY ET AL., "A 6-Month Radonmized, Placebo-Controlled, Dose-Ranging Trial of Topiramate for Weight Loss in Obesity", <i>Obesity Research</i> , 11:722-733 (2003)	
	A78	BROOKHAVEN NATIONAL LABORATORY (BNL), "Therapeutic Drug Blocks Nicotine's Effects on Brain Chemistry", (November 8, 2001), <a href="http://www.bnl.gov/bnlweb/pubaf/pr/2001/bnlpr110801.htm">http://www.bnl.gov/bnlweb/pubaf/pr/2001/bnlpr110801.htm</a> .	
	A79	L. HENDERSON ET AL., "J & J will not pursue Topamax for Obesity", <i>BTech News</i> , (February 8, 2002) ( <a href="http://www.btechnews.com">www.btechnews.com</a> ).	
	A80	JOHNSON ET AL., "Oral topiramate for treatment of alcohol dependence: a randommized controlled trial", <i>Lancet</i> , 361(9370): 1666-7 (May 17, 2003).	
	A81	LINDAHL ET AL., "Characterization of Fluids from the Stomach and Proximal Jejunum in Men and Women", <i>Pharmaceutical Research</i> , Vol. 14, No. 4, pp. 497-502 (1997)	
	A82	<i>The Physicians' Desk Reference</i> , 57 <sup>th</sup> Ed., pp. 2501-2503 (2003)	
	A83	STEIN, "Epilepsy Drugs May Curb Obesity", <i>Wash. Post</i> , p. A03 (Oct. 7, 2003)	
	A84	STEIN, International Diabetes Federation (IDF): Topiramate Shows Potential for Weight Loss Obese Diabetics" (August 26, 2003), <a href="http://www.docguide.com/news/content.nsf/news/8525697700573E1885256D8E005999FC">www.docguide.com/news/content.nsf/news/8525697700573E1885256D8E005999FC</a> .	

<b>Examiner Signature</b>	<b>Date Considered</b>
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